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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/703,809	10/30/2000	Jeff L. DeJong	119941-1083	3391

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/703,809	DEJONG, JEFF L.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,33,34,68,69 and 71-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2,33,34,68,69 and 71-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1☐ Certified copies of the priority documents have been received.

2☐ Certified copies of the priority documents have been received in Application No. _____.

3☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

5) ☐ Notice of Informal Patent Application (PTO-152)

DETAILED ACTION

Applicants amendment canceling claims 35-67 and 70, Paper No. 9, 10/16/2002, is acknowledged. Claims 2, 33, 34, 68, 69 and 71-85 are at issue and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 2, 33, 34, 68, 69 and 71-85 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the examiner has failed to make a prima facie case that restriction is required because the previous requirement for restriction provides no reason why the inventions as claimed are either independent or distinct, but it merely provides a conclusion that such is the case. This argument is not found persuasive because as was stated in the previous office action:

> The inventions are distinct, each from the other because of the following reasons:
>
> Inventions I and II are unrelated. Inventions are unrelated if it can be shown that **they are not disclosed as capable of use together** and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the ALF or SALF polypeptides of Group I, and the nucleic acid encoding the ALF or SALF polypeptides of Group II **each comprise a chemically unrelated structure capable of separate manufacture, use and effect**. The peptides of Group I are comprised of amino acid sequence and the DNAs of Group II are comprised of nucleic acid sequence. The DNA has other utility besides encoding protein such as a hybridization probe, and the proteins can be made synthetically. Additionally, the protein can be used to perform specific biological function(s) which are independent of the function(s) of the DNA molecule. The protein has other utility such as for the production of antibodies.

Specification

The disclosure is objected to because of the following informalities:

As discussed below with respect to the claims and reference to specific sequence identifiers, the specification sometimes recites "SEQ ID NO.:" (i.e. page 44, lines 8 and 10) and sometimes recites "SEQ ID NO." (i.e. page 13, lines 7 and 9), "SEQ ID NO" (i.e. page 13, line 13). It is suggested that applicants maintain consistency throughout the application.

Throughout the specification "...transcriptional factor..." is recited numerous times (i.e. 5, lines 21, 28, page 11, line 6, etc...) It is believed that this should be "...transcription factor..."

Appropriate correction is required.

Claim Objections

Claims 2, 33, 34, 68, 69, 71-85 is objected to because of the following informalities:

Claim 2 recites the following sequence identifier "SEQ ID NO. ", whereas claims 34, 68, 69, 73, 78, 81 and 85 recite "SEQ ID NO.:". Claims 71 and 79, recite "SEQ ID NO:". It is suggested that applicants maintain consistency throughout the application.

Claims 71-85 recite "ALF" and "SALF", which are each acronyms. It is suggested

invention.

Claims 76, 77, 84 recites "...human **transcriptional** factor...". It is believed that in fact applicants invention is drawn to a "...human **transcription** factor..." Throughout the specification "...human testis-specific transcriptional factor..." is also recited numerous times.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 33, 34, 68, 69 and 71-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in the that the recitation "A composition comprising a polypeptide sequence set out in SEQ ID NO. 2 ..." is unclear. Specifically the claim is unclear in "a composition comprising a polypeptide sequence" and in "a polypeptide sequence in SEQ ID NO. 2" It is believed that applicants intent is that the claimed "composition comprises a polypeptide, wherein said polypeptide comprises an amino acid sequence of SEQ ID NO. 2..." For the purpose of advancing prosecution this is how the claim is interpreted.

equivalent. A functionally equivalent polypeptide may encompass a variety of different biological activities. These include but are not limited to immunological activity, such as

acting as an antigen for an antibody; regulatory activity, such as that exhibited by many proteins which control transcription and/or translation of not only their encoding nucleic acids but other nucleic acids as well; or enzymatic activity.

Claim 69 is indefinite in that it is drawn to the isolated polypeptide of claim 20. Claim 20 which was drawn to a nucleic acid is now cancelled. For the purpose of advancing prosecution claim 69 is interpreted as if it depended from claim 68.

Claim 33 (claim 34 dependent on) and 68 (claim 69 dependent on) are indefinite in that the recitation "mature polypeptide" is unclear, especially as the mature polypeptide relates to the nucleic acid segment that is at least 95% identical to SEQ ID NO.: 1.

Claims 71 (72-78 dependent on) and 79 (80-85 dependent on) are indefinite in the recitation "ALF protein" as the specification fails to teach which identifying characteristics distinguish an "ALF protein" from other proteins, which are distinct in sequence from SEQ ID NOs . 2 or 4. Thus it is unclear what characteristics of a protein distinguish it such that it may be considered to be within this class.

Claims 71 (72-78 dependent on) and 79 (80-85 dependent on) are further indefinite in the recitation "...substantially homologous ..." It is unclear as to the what the metes and bounds of the genus of those nucleic acid sequences that are considered by applicants to be "substantially homologous" to the recited SEQ ID NO. Outside of those which that protein encoded by SEQ ID NO. 3, there is nothing to suggest that

what is considered substantially homologous varies widely depending on the individual

situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NO:3, a sequence must be to be included within the scope of these claims.

Claims 71 (72-78 dependent on) and 79 (80-85 dependent on) are further indefinite in the recitation "...the coding strand of the gene sequence set forth in SEQ ID NO:3 ..." It is unclear what applicants consider the coding strand of the gene sequence set forth in SEQ ID NO: 3. Is it applicants intent that this recitation refers to a specific "strand" set forth in SEQ ID NO: 3 or is it applicants intent that this recitation refers to the "coding region" set forth in SEQ ID NO: 3? Is SEQ ID NO: 3 as listed in the sequence listing not a single strand? Is this recitation the same as the "...the nucleic acid sequence set forth in SEQ ID NO:3 ..."

Claims 78, 82 and 85 recite the limitation "said SALF protein" in claims 74 and 77, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claims 78 is indefinite in the recitation "SALF protein" as the specification fails to teach which identifying characteristics distinguish an SALF protein" from other proteins, which are distinct in sequence from SEQ ID NO: 4. Thus it is unclear what characteristics of a protein distinguish it such that it may be considered to be within this class.

Claims 83 and 84 recite the limitation "said non-ALF protein" in claim 82. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 33, 68, 71, 72, 74-78, 79, 80 and 82-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 33, 68, are drawn to a composition comprising a polypeptide sequence set out in SEQ ID NO. 2 and fragments thereof or those which are functionally equivalent (claim 2), and those isolated mature polypeptides having an amino acid sequence encoded by a nucleic acid sequence that is at least 95% identical to SEQ ID NOs: 1 or 3 (claims 33 and 68). Claims 71, 72, 74-78, 79, 80 and 82-85 are drawn to a purified ALF protein encoded by an oligonucleotide comprising a nucleic acid sequence substantially homologous to the coding strand of the gene sequence set forth in SEQ ID NOs. 1 or 3 (claims 71, 72, 79 and 80) and fusion proteins comprising said ALF protein (claims 74-78 and 82-85).

The specification, however, only provides the representative species of ALF proteins having the amino acid sequence of SEQ ID NO: 2 and 4. There is no disclosure of any particular structure to function/activity relationship in the disclosed

these proteins by any identifying structural characteristics or properties other than the characteristics recited in claims, for which no predictability of function is apparent.

The genus of proteins that are claimed is a large variable genus with potentiality of comprising many different proteins. Therefore, many functionally unrelated proteins are encompassed within the scope of these claims. The specification discloses only species of each claimed genus (i.e. having the amino acid sequence SEQ ID NO: 2 and 4) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 2, 33, 68, 71, 72, 74-78, 79, 80 and 82-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated ALF protein having the amino acid sequence of SEQ ID NO: 2 or 4, does not reasonably provide enablement for any functional equivalent of a protein comprising the amino acid sequence of SEQ ID NOs: 2 or 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

Claims 2, 33, 68, are so broad as to encompass any composition comprising a polypeptide sequence set out in SEQ ID NO. 2 and fragments thereof or those which are functionally equivalent (claim 2), and any mature polypeptides having an amino acid sequence encoded by a nucleic acid sequence that is at least 95% identical to SEQ ID NOs: 1 or 3 (claims 33 and 68). Claims 71, 72, 74-78, 79, 80 and 82-85 are so broad as to encompass any purified ALF protein encoded by an oligonucleotide comprising a nucleic acid sequence substantially homologous to the coding strand of the gene sequence set forth in SEQ ID NOs. 1 or 3 (claims 71, 72, 79 and 80) and fusion proteins comprising said ALF proteins (claims 74-78 and 82-85).

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of compositions, proteins and fusion proteins broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the teachings of those proteins having the amino acid sequence of SEQ ID NO: 2 and 4.

art to screen for multiple substitutions or multiple modifications, as encompassed by the

instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any ALF protein because the specification does **not** establish: (A) regions of the ALF protein structure which may be modified without effecting transcription factor activity; (B) the general tolerance of ALF proteins to amino acids to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired activity and the fact that the relationship between the sequence of a polypeptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it

those polypeptides of the claimed genus having the desired activity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any ALF protein. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those DNAs having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b)as anticipated by Ma et al. (Genes and Development 7(11):2246-2257, Nov 1993).

Ma et al. teach the cloning and identification of a cDNA clone encoding the largest subunit of TFIIA. The cDNA taught by Ma et al. has a best local similarity score

composition comprising a functional equivalent of the polypeptide sequence of SEQ ID NO : 2.

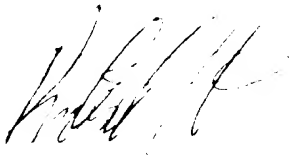
Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652